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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,329

09/25/2003

Hugh Herr

0050.2061-000

5686

21005

7590

11/01/2007

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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EXAMINER

FLORY, CHRISTOPHER A

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

11/01/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Interview Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/671,329		HERR ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Christopher A. Flory		3762	

All participants (applicant, applicant's representative, PTO personnel):

(1) Christopher A. Flory.

(3) Hugh Herr.

(2) Scott Pierce.

(4) \_\_\_\_\_.

Date of Interview: 29 October 2007.

Type: a) ☒ Telephonic    b) ☐ Video Conference  
c) ☐ Personal [copy given to: 1) ☐ applicant    2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes    e) ☐ No.  
If Yes, brief description: \_\_\_\_\_.

Claim(s) discussed: 1-32.

Identification of prior art discussed: Beard et al. (US 5,112,296); Stein (US 5,643,332); Swain et al. (US 6,507,757); Johnson et al. (US 5,662,693); Horst (US 6,996,882).

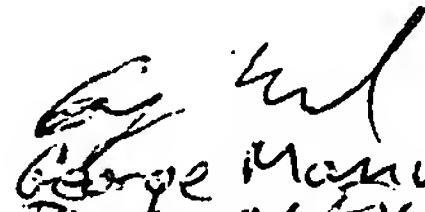
Agreement with respect to the claims f) ☒ was reached.    g) ☐ was not reached.    h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

  
George Manuel  
Primary Examiner  
Examiner's signature, if required

## Summary of Record of Interview Requirements

### Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

### Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

#### Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

#### 37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,  
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

### Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The Examiner would like to thank Mr. Pierce and Dr. Herr for their constructive discussion during this morning's interview. As a preliminary note, it was brought to the attention of the Examiner that an amendment has recently been filed in reply to the Office Action mailed 18 May 2007, although said amendment was not available to the Examiner by the time of the interview. As a result of today's conference and additional Supplemental Amendment will be filed by the Applicant, both to be considered by the Examiner in an updated search.

Dr. Herr summarized the invention as a treatment for an ankle-foot condition, specifically drop foot, in which a patient exhibits anterior muscle weakness. In the normal healthy biological system, the muscle of the ankle joint can change both position (angle) and stiffness (rotational impedance) independently from one another, and is additionally able to vary impedance without a change in position (i.e. a tensing of the muscles) as well as change position without varying impedance (e.g. free swing) in order to greatly improve stability control. According to Dr. Herr, this independent variability is not possible with a simple motor system, such as a dc motor, which can vary the angle but not the stiffness and damping of the joint.

Regarding Beard'296, it was proposed by Applicant that the disclosed method is to mechanically lift the foot using a motor actuator to prevent toe strike, but this lifting action does not modulate the joint impedance. Examiner presented the interpretation that when the foot is lifted and locked in position, it is prohibitive of the patient to selectively plantar flex the foot, and therefore represents high impedance to the joint motion, whereas when the slip coupling is activated upon heel strike, the ankle freely moves to allow foot contact and walk-over, which represents a lowered, or varied, system impedance. Given this interpretation, Beard'296 could reasonably be seen to disclose an ankle foot orthosis that varies impedance of the ankle joint. In order to overcome this interpretation, Applicant proposed that Beard'296, although possibly seen as impeding movement of the ankle joint, does not modulate the joint stiffness or joint damping property when providing such an impedance. The impedance provided by Beard'296 is all or none, wherein during the swing phase the foot is locked to prevent movement (foot drop), and upon heel strike the slip coupling effectively unlocks the joint to again allow free movement of the device and the ankle. A simple lock and release control of the ankle does not equate to modulating the mechanical properties of stiffness or damping exhibited by the joint. Alternatively, it was suggested that the claims be amended to convey that the impedance is being modulated continuously or more than once in an updating manner during each swing phase and walk cycle to further distinguish from the Beard'296 reference. Still alternatively, it was suggested to amend the independent claims to include a limitation wherein the modulation to the joint impedance is adaptive in nature such that information from each gait cycle causes further modulations that vary the joint impedance response from one gait cycle to the next, which both the Applicant and the Examiner see as a substantive aspect of the novelty of the invention.

Regarding Swain'757, it is proposed that the system functions in a similar fashion to the Beard'296, wherein there is an all-or-none locking of the ankle joint (via anterior muscle stimulation and contraction) during swing phase and complete release of muscle contraction during heel strike to allow unaided ankle motion for walk-over. The stimulation envelope of Figures 2-4 shows a rising edge ramp and a falling edge ramp to the stimulation pattern. However, these edge regions are found to be negligible artifacts of real versus ideal control systems, and would not be sufficient to provide modulation of ankle joint stiffness being on the order of 300 microseconds in length, relative to a stimulus duration of 0.5 to 6 seconds (column 6, lines 15-37 and 55-66). Therefore, for similar reasons as Beard'296, Swain'757 is found to be lacking in disclosure of modulating the mechanical properties of stiffness and damping in the ankle joint in an adaptive manner.

Stein'332 is found to be similarly deficient in disclosing modulation of stiffness and damping in the ankle joint. Stein'332 again discloses a system in which the joint is either locked at an upward position to avoid toe strike or fully released to allow free motion during heel strike and walk-over. A modulation of stiffness and damping within the ankle joint itself would require a graded range of stimulation possibilities between these two states of an all-or-none control.

Johnson'693 similarly discloses a system with an all-or-none foot lift during swing and release during heel strike. Although the Johnson'693 system employs a pneumatic actuator with a series spring (Figure 3c), the spring constant  $k$ , which in this system represents the joint stiffness, stays constant regardless of the position or amount of contraction of the pneumatic actuator. A varying of the joint impedance would require a varying of the constant  $k$ . Therefore, Johnson'693 again lacks modulation of the stiffness and damping in the ankle joint.

Horst'882 similarly discloses a system with a dc motor actuator which, for reasons similar to the other discussed references, lacks the ability to modulate the mechanical stiffness and damping properties of the ankle joint in an adaptive manner.